



BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2015-0008; NIOSH-282]

International Labour Office (ILO) Reference Radiographs

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information and comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease and Prevention is collaborating with the Labour Inspection, Labour Administration and Occupational Safety and Health Branch of the International Labour Office (ILO) in developing a set of digital reference radiographs for the ILO International Classification of Radiographs of Pneumoconiosis (ILO Classification). The current ILO Classification depends on 22 standard reference radiographs that are used to formally identify and characterize pneumoconiosis and related pulmonary abnormalities arising from

occupational exposure. The original standards were based on film radiography, but the advent of digital radiography has led to the need for reference standards based on digitally-acquired images. NIOSH is assisting the ILO in the process of identifying such digital images.

For this purpose, NIOSH is requesting trained users of the ILO Classification (e.g., NIOSH B-Readers [1] and other such experts) to submit comments regarding any of the current standard reference images that are felt to be deficient and for which improvements could be made. The current structure and format of the ILO Classification is to remain unchanged at the present time. NIOSH is not soliciting comments on the ILO Classification itself. Comments received on the ILO Classification will be considered irrelevant to the purpose of this docket.

DATES: Electronic or written comments must be received by

[insert date 60 days from posting].

ADDRESSES: You may submit comments, identified by CDC-2015-0008 and docket number NIOSH-282, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.

Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34,

Cincinnati, OH 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC-2015-0008; NIOSH-282). All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. All electronic comments should be formatted as Microsoft Word. For access to the docket to read background documents or comments received, go to www.regulations.gov. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226.

FOR FURTHER INFORMATION CONTACT: Michael Attfield, 1095

Willowdale Road, Morgantown, WV 26505-2888, telephone (304) 285-5737 (this is not a toll free number).

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Background: Chest radiographs (X-Rays) provide critical medical information for the assessment of the pneumoconioses and related

disorders in individuals, for example, those caused by inhaling coal, silica, and asbestos dusts [2]. Prior to 1950, the information evident on a radiograph could only be interpreted qualitatively. However in 1950, the International Labour Office (ILO) established a more quantitative system whereby the various parenchymal and pleural changes could be formally recognized and categorized. The quantitative system is not intended for the medical diagnosis of the pneumoconioses and related occupational diseases, but has proved invaluable for the accurate and reliable identification and characterization of such diseases and disorders in many scientific and administrative applications, including research into disease causation, evaluation of risk in terms of dust exposure, disease surveillance, disease prevention, and worker compensation. The ILO has periodically held meetings of experts with the intent of improving and refining the original classification scheme. The current edition is the International Classification of Radiographs of Pneumoconiosis, Revised Edition 2011 [3].

The ILO Classification, as of the 2000 revision, consists of 22 standard reference radiographic films. These films were selected to demonstrate a variety of types and severities of lung abnormalities that frequently arise from occupational dust exposure. Proper use of the classification involves a visual

comparison of the test subject's X-Ray film side-by-side with the standards. The test subject is assigned the classification pertaining to the standard radiograph or radiographs to which it is most similar in appearance, i.e., Category 0/0, 1/1, 2/2, or 3/3; and the types p/p, q/q, r/r, s/s, t/t, or u/u, where applicable. The person undertaking the classification, typically a physician formally trained in the use of the ILO Classification, completes a data entry sheet where they record their classifications of each of the various abnormalities. In addition, ancillary information on the quality of the radiograph and the presence of other medical findings is noted.

The ILO classification was developed and used for over 50 years solely in conjunction with film radiography. In recent years radiographic technology has advanced to digital imaging. This poses severe problems for the use of the ILO Classification since the test subject's image must be viewed on a computer terminal screen while the standards can only be seen on a separate film viewing box. This results in the process being extremely cumbersome, while intrinsic differences in the appearance of film versus digital images interfere with the proper assessment of abnormality. To minimize these problems, the ILO released a set of digitized images in 2011. These images

are digitized views of the existing film images, obtained by formally scanning each film to a digital file image.

While digitizing the current standard reference films removed the need to employ a light box, as both images could now be viewed on the same computerized image display system alongside that showing the subject's radiograph, it did not eliminate the problems arising from different inherent appearances between the original film and the digital test images, since those still remained in the digitized versions. Ultimately, the best means to remove the potentially interfering visual differences from the comparison between the digitally-acquired chest radiographic image and the reference image is to select new digitally-acquired reference images.

NIOSH is collaborating with and assisting the ILO in identifying a set of 22 digital images, each of which is intended to mimic as closely as possible the type and severity of abnormality evident on each of the current standard films/digitized images. There is no intention to modify or alter the underlying structure or format of the existing ILO Classification. The final outcome of this exercise will simply be an additional set of standard reference images, derived from digitally-acquired images.

In pursuing this objective both NIOSH and the ILO are aware that users of the classification may feel that one or more of the existing standard references do not optimally demonstrate the specified parenchymal or pleural findings. Appendix C of the manual that accompanies the ILO Classification [2] provides comments on each of the current standard radiographs. Comments range from issues of quality (e.g., unsharp, overexposed), excluded regions (e.g., costophrenic angles), and other factors. In addition, there is no category 1/1 s/s standard as there should be. Instead a 1/1 s/t is used. Moreover, only single quadrant views are available for all of the u/u type small opacity severities when individual full chest image standards would be better. To the extent possible, it is hoped to correct these known issues during the identification of new digital images.

In addition to the published issues, regular users of the ILO Classification may feel that certain of the standard reference radiographs are sub-optimal in some way or another. For example, perhaps the appearances of a particular standard are generally felt to be at variance with its formally-designated degree of abnormality. In addition, there may be other factors where there are opportunities for improvement.

NIOSH and the ILO, in selecting the new digital standard images, wish to correct any technical issues affecting the current standard reference radiographs. To be able to do this, they require access to information on perceived problems with the current standards. This docket is a request for information from interested parties on perceived issues with any of the current standards. This request in no way involves comment on the structure and content of the ILO Classification per se. NIOSH and the ILO will summarize the comments received on each of the standard radiographs, and employ that information in the derivation of the new digital standard reference radiographs.

Information Needs: NIOSH is seeking additional data and information to ensure that generally perceived technical issues affecting any of the current ILO Classification standard radiographs are addressed in the development of a set of digital standard radiographs. Information is particularly needed for:

- 1) The standard reference title to which your submitted comments apply. For small opacities please state 'small opacities' and the profusion (0/0, 1/1, 2/2, or 3/3, and the type (p/p, q/q, r/r, s/s, t/t, or u/u, where applicable) for which you are supplying comments. For large opacities please state 'large

opacities' and the stage (A, B, C). For pleural abnormalities, please state 'pleural'.

2) For radiographs concerning small opacities, please note whether the standard radiograph shows appearances consistent with its designated profusion, and if not, what profusion you believe it shows.

3) For radiographs concerning small opacities, please note whether the standard radiograph shows appearances consistent with its designated type, and if not, what type you believe it shows.

4) For large opacities, please note whether the standard radiograph shows appearances consistent with its designated stage, and if not, what stage you believe it shows.

5) For the composite radiograph showing pleural abnormalities, please note your concerns with each segment.

6) For all, please note any problems associated with other factors that impact its optimal reliability as a standard, indicate their effect on classification, and suggest a solution for improvement.

References

1. NIOSH [2012]. Chest Radiography: The NIOSH B Reader Program.
<http://www.cdc.gov/niosh/topics/chestradiography/breader.html>
2. NIOSH [2011]. Chest Radiography: Evaluating Occupational Lung Disorders.
<http://www.cdc.gov/niosh/topics/chestradiography/default.html>.
3. ILO [2011]. The ILO International Classification of Radiographs of Pneumoconioses.
http://www.ilo.org/safework/info/WCMS_108548/lang--en/index.htm.

Dated: March 30, 2015.

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